

**Notice of Allowability****Application No.**

09/621,341

**Examiner**

Pensee T. Do

**Applicant(s)**

ENPUKU, KEIJI

**Art Unit**

1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on December 22, 2003.
2. ☒ The allowed claim(s) is/are 16-26.
3. ☒ The drawings filed on 15 October 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>March 16, 2004</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                               |
|   | 9. <input type="checkbox"/> Other _____.   |

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. David Blumenthal on March 16, 2004.

The application has been amended as follows:

In the specification, replace the abstract with the attached abstract.

Claim 16, line 1, "and a Superconducting Quantum Interference Device" is deleted.

Claim 16, "label" (second occurrence) in line 11, and "label" in line 13, is replaced with --labeled analyte--.

Claim 16, line 11, "use of said " is replaced with --using a--.

Claim 18, line 3, "label" is replaced with --labeled analyte--.

Claim 20, line 1, "and a Superconducting Quantum Interference Device" is deleted.

Claim 20, line 12, and line 14, "label" is replaced with --labeled analyte--.

Claim 20, line 12, "use of said " is replaced with --using a--.

The following is an examiner's statement of reasons for allowance:

The prior arts fails to teach a method of immunoassay with a magnetic material label comprising one of the steps of while continuing to apply a magnetic field which

magnetizes the magnetic material label, detecting the magnetizing the magnetic material labeled analyte by using a superconducting quantum interference device, a magnetic flux component which is generated from the magnetized magnetic material labeled analyte and which is at a right angle to the direction of the magnetic field which magnetizes said magnetic material label.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/621,341  
Art Unit: 1641

Page 4

Pensee T. Do  
Patent Examiner  
March 17, 2004

*Christopher L. Chin*  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 / 641

### **Abstract**

The present invention relates to an immunoassay and an apparatus for the same. A method of the present invention comprises following processes: (1) an analyte is labeled with a magnetic label to detect antigen-antibody reaction, (2) the magnetic material label is magnetized by a magnetic field, (3) the magnetized magnetic material label detected by a SQUID which detect a magnetic field having right angle to the magnetic field. At the same time, the present invention contains an apparatus to execute the method provided by the present invention. The apparatus comprises a magnetic field generation means that generates a magnetic field to magnetize the labels. The apparatus comprises a SQUID that measures magnetic field.